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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/031,938 | 07/22/2002 | Srinivas Kaveri | TJK/209 | 8718 |

27717 7590 12/31/2007
SEYFARTH SHAW LLP
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CHICAGO, IL 60603-5803

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| EXAMINER |
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MEAH, MOHAMMAD Y

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| ART UNIT | PAPER NUMBER |
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1652

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| MAIL DATE | DELIVERY MODE |
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12/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/031,938

Applicant(s)

KAVERI ET AL.

Examiner

Mohammad Meah

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-123,141-143 and 151-154 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 86-123,141-143 and 151-154 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

With supplemental amendment of this application, the applicant, on dates 10/17/07 amended the claims 111-113, 121-123 and 141-143 for further examination. These claims are elected for examination on 07/15/2004 by the applicant from the election/restriction office action of 5/20/04.

However the election restriction of the claims and subsequent incorporation of the claims and examinations of claims 111-113, 121-123 and 141-143 based on applicants argument in the previous office action of date 9/15/04 was erroneous as a result claims 111-113, 121-123 and 141-143 comprise multiple inventions. Therefore further and proper restriction of the elected 111-113, 121-123 and 141-143 is required as shown bellow:

Election/Restrictions

During preliminary amendment of this application on date 09/15/2004 , the applicants', election with traverse of the prior electeion/restriction had been considered wrongfully by the previous examiner.

Applicants arguments of No lack of unity was found by the international is answered as follows:

The traversal is on the ground(s) that there was no lack of unity requirement made in the international phase. Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement previously applied. With regard to the finding of unity of invention in the international phase, it is noted that even if the International Authority found unity of invention regarding the instant claims, according to 37 CFR 1.499, if the Examiner finds that a national stage application lacks unity of invention under 37 CFR 1.475, the

Examiner may in an Office action require the applicant in the response to that action to elect an invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the Examiner. Thus a finding of unity of invention in the international stage is not binding on the examination during national phase examination.

Therefore Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 86-110, drawn to method of detecting antifactor VIII allo-antibodies.

Group II, claims 111-116, 143-143, drawn to polypeptide type inhibitor comprising SEQ ID NO: 1, 2, 3.

Group III, claims 117--123, drawn to method neutralizing catalytic anti-factor VIII allo-antibodies using peptide type inhibitor.

Group IV, claims 151--154, antifactor VIII allo-antibodies.

The inventions listed in Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical features of Groups II and IV are products. The polypeptide of group II has distinct structure, function and properties that are not shared by antibodies of group IV.

Therefore group II and IV do not share their technical features.

The technical features of Group I and III are different method steps using different reagents and result different outcome. Thus, the technical feature of Group I is not shared with that of group III.

Group I and IV share a technical feature, a product (antifactor VIII allo-antibodies).

Group II and III share a technical feature, a product (polypeptide type inhibitor).

However technical feature linking group I-IV, antifactor VIII allo-antibodies and their detection, do not constitute a "special technical feature" as defined by PCT Rule 13.2, because it does not claim a feature which defines a contribution over the prior art as antifactor VIII allo-antibodies and their detection is taught by Saenko, et al (J. boil. chem. 1996, pp 27424-27430, from IDS).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

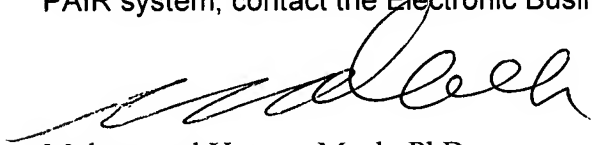
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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